

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: de Jong *et al.*

Serial No.: 10/086,745

Conf. No.: 8781

Cust. No.: 24961

Filed: February 28, 2002

For: **METHODS FOR DELIVERING NUCLEIC  
ACID MOLECULES INTO CELLS AND  
ASSESSMENT THEREOF**

Art Unit: 1636

Examiner: Unassigned



CERTIFICATE OF MAILING BY "EXPRESS MAIL"

"Express Mail" Mailing Label Number  
EV 335464912 US

Date of Deposit August 6, 2003

I hereby certify that this paper is being deposited with the United States Postal "Express Mail Post Office to Addressee" Service under 37 CFR §1.10 on the date indicated above and addressed to:

Commissioner for Patents,  
U.S. Patent and Trademark Office  
P.O. Box 2327  
Arlington, VA 22202

08/06/03  
Date

  
Michael Lough

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT IN ACCORDANCE  
WITH 37 C.F.R. §§ 1.97-1.98**

Commissioner for Patents  
U.S. Patent and Trademark Office  
P. O. Box 2327  
Arlington, VA 22202

Dear Sir:

Since this Supplemental Information Disclosure Statement is filed before receipt of a first Office Action on the merits for the above-captioned application, no fee is due. If it is determined that a fee is due, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-1213.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all references known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Supplemental Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Form PTO-1449 (3 pages) is provided herewith in connection with the above-captioned application. The cited documents listed on Form PTO-1449 and marked with an asterisk are not provided herewith as they have been previously provided in connection with U.S. Serial No. 09/815,981, which is relied upon for an earlier filing date in accordance with 35 U.S.C. §120.

**U.S.S.N. 10/086,745**

**de Jong *et al.***

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

The documents listed on the Form PTO-1449 are in the English language. Hence, in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

Applicant also makes known to the Examiner the following U.S. application, which is commonly owned and/or has one or more inventors in common in the instant application:

<b>U.S.S.N.</b>	<b>Filing Date</b>	<b>Docket No.</b>
10/428,653	05/01/03	24601-426

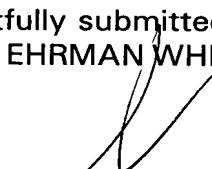
Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the references, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(h), the filing of this Supplemental Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

\* \* \*

Applicant respectfully requests that the Examiner review the foregoing references and information and that they be made of record in the file history of the above-captioned application.

Respectfully submitted,  
HELLER EHRLMAN WHITE & MCAULIFFE LLP

By:

  
Stephanie L. Seidman  
Registration No. 33,779

Attorney Docket No. 24601-416C

**Address all correspondence to:**

Stephanie L. Seidman

HELLER EHRLMAN WHITE & MCAULIFFE LLP

4350 La Jolla Village Drive, 7th floor

San Diego, CA 92122-1246

Telephone: 858 450-8400

Facsimile: 858 587-5360

email: [sseidman@HEWM.com](mailto:sseidman@HEWM.com)

FORM PTO-1449



LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 24601-416C	SERIAL NO. 10/086,745	CONFIRM NO. 8781
	APPLICANT de Jong et al.	CUSTOMER NO. 24961	
	FILING DATE February 28, 2002	GROUP 1636	

\* If an asterisk is placed beside the reference number, a copy is NOT provided because the reference was previously cited by or submitted to the PTO in a prior application that is identified in the statement and relied upon for an earlier filing date under 35 U.S.C. 120, 37 C.F.R. § 1.98(d).

+ Derwent English language abstract and/or English translation provided.

### U.S. PATENT DOCUMENTS

EXAMINER INITIAL	*Ref. Code	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE

### FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	*Ref. Code	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	Translation Yes      No

### OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	*A	Albertsen <i>et al.</i> , "Construction and characterization of a yeast artificial chromosome library containing seven haploid human genome equivalents", <i>PNAS</i> , <u>87</u> :4256-4260 (1990)
	*B	Brown <i>et al.</i> , "Artificial chromosomes: ideal vectors?", <i>TIBTech</i> , <u>18</u> :218-223 (2000)
	*C	Cavazzana-Calvo <i>et al.</i> , "Gene Therapy of Human Severe Combined Immunodeficiency (SCID)-X1 Disease", <i>Science</i> , <u>288</u> :669-672 (2000)
	*D	Cocchia <i>et al.</i> , "Recovery and potential utility of YACs as circular YACs/BACs", <i>Nucl. Acids Res.</i> , <u>28</u> (17):e81 i-viii (2000)
	*E	Dausset <i>et al.</i> , "The CEPH YAC Library", <i>Behring Inst. Mitt.</i> , <u>91</u> :13-20 (1992)
	*F	Foecking <i>et al.</i> , "Powerful and versatile enhancer-promoter unit for mammalian expression vectors", <i>Gene</i> , <u>45</u> :101-105 (1986)
	*G	Giraldo <i>et al.</i> , "Size matters: use of YACs, BACs and PACs in transgenic animals", <i>Transgenic Res.</i> , <u>10</u> :83-103 (2001)
	*H	Han <i>et al.</i> , "Development of Biomaterials for Gene Therapy", <i>Mol. Therapy</i> , <u>2</u> (4):302-317 (2000)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Title: **METHODS FOR DELIVERING NUCLEIC ACID MOLECULES INTO CELLS AND ASSESSMENT THEREOF**

FORM PTO-1449 LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 24601-416C	SERIAL NO. 10/086,745	CONFIRM NO. 8781
	APPLICANT de Jong et al.	CUSTOMER NO. 24961	
	FILING DATE February 28, 2002	GROUP 1636	

\* If an asterisk is placed beside the reference number, a copy is NOT provided because the reference was previously cited by or submitted to the PTO in a prior application that is identified in the statement and relied upon for an earlier filing date under 35 U.S.C. 120. 37 C.F.R. § 1.98(d).

+ Derwent English language abstract and/or English translation provided.

#### OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

*I	Hem <i>et al.</i> , "Saphenous vein puncture for blood sampling of the mouse, rat, hamster, gerbil, guineapig, ferret and mink", <i>Laboratory Animals</i> , <u>32</u> :364-368 (1998)
*J	Jacobovits <i>et al.</i> , "Germ-line transmission and expression of a human-derived yeast artificial chromosome", <i>Nature</i> , <u>362</u> :255-258 (1993)
*K	Lange-Gustafson <i>et al.</i> , "Purification and Properties of Int-h, a Variant Protein Involved in Site-specific Recombination of Bacteriophage $\lambda$ ", <i>J. Biol. Chem.</i> , <u>259</u> (20):12724-12732 (1984)
*L	Larin <i>et al.</i> , "A method for linking yeast artificial chromosomes", <i>Nucl. Acid Res.</i> , <u>24</u> (21):4192-4196 (1996)
*M	Libert <i>et al.</i> , "Construction of a Bovine Genomic Library of Large Yeast Artificial Chromosome Clones", <i>Genomics</i> , <u>18</u> :270-276 (1993)
*N	Lorbach <i>et al.</i> , "Site-specific Recombination in Human Cells Catalyzed by Phage $\lambda$ Integrase Mutants", <i>J. Mol. Biol.</i> , <u>296</u> :1175-1181 (2000)
*O	Lowry, R., "Two-Factor ANOVA with Repeated Measures on One Factor", <a href="http://faculty.vassar.edu/lowry/anova2corr.html">http://faculty.vassar.edu/lowry/anova2corr.html</a> (2000)
*P	Luo <i>et al.</i> , "Synthetic DNA delivery systems", <i>Nature Biotechnol.</i> , <u>18</u> :33-37 (2000)
*Q	Marschall <i>et al.</i> , "Transfer of YACs up to 2.3 Mb intact into human cells with polyethylenimine", <i>Gene Therapy</i> , <u>6</u> :1634-1637 (1999)
*R	Miller <i>et al.</i> , "int-h: an <i>int</i> Mutation of Phage $\lambda$ That Enhances Site-Specific Recombination", <i>Cell</i> , <u>20</u> :721-729 (1980)
*S	Mountain <i>et al.</i> , "Gene therapy: the first decade", <i>TIBTECH</i> , <u>18</u> :119-128 (2000)
*T	NCBI Nucleotide, Gene Bank Accession No. NC001416
*U	Osborne <i>et al.</i> , "Gene therapy for long-term expression of erythropoietin in rats", <i>Proc. Natl. Acad. Sci. USA</i> , <u>92</u> :8055-8058 (1995)
*V	Palmieri <i>et al.</i> , "Construction of a pilot human YAC library in a recombination-defective yeast strain", <i>Gene</i> , <u>188</u> :169-174 (1997)

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Title: **METHODS FOR DELIVERING NUCLEIC ACID MOLECULES INTO CELLS AND ASSESSMENT THEREOF**

FORM PTO-1449



LIST OF PATENTS AND PUBLICATIONS FOR  
APPLICANT'S INFORMATION DISCLOSURE  
STATEMENT

ATTY. DOCKET NO. 24601-416C	SERIAL NO. 10/086,745	CONFIRM NO. 8781
APPLICANT de Jong et al.	CUSTOMER NO. 24961	
FILING DATE February 28, 2002	GROUP 1636	

\* If an asterisk is placed beside the reference number, a copy is NOT provided because the reference was previously cited by or submitted to the PTO in a prior application that is identified in the statement and relied upon for an earlier filing date under 35 U.S.C. 120. 37 C.F.R. § 1.98(d).

+ Derwent English language abstract and/or English translation provided.

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

*W	Schedl <i>et al.</i> , "A method for the generation of YAC transgenic mice by pronuclear microinjection", <i>Nucl. Acid Res.</i> , <u>21</u> :4783-4787 (1993)
*X	Shen <i>et al.</i> , "A structurally defined mini-chromosome vector for the mouse germ line", <i>Current Biology</i> , <u>10</u> :31-34 (2000)
*Y	Sigma Catalog, Biochemicals and Regents for Life Science Research, Molecular Biology, pp. 221, 227, 275, 363, 411, 543, 576, 909 (1998)
*Z	Stocum <i>et al.</i> , "Regenerative biology: A millenial revolution", <i>Cell and Devel. Biol.</i> , <u>10</u> :433-440 (1999)
*AA	Stocum <i>et al.</i> , "Regenerative biology and engineering: strategies for tissue restoration", <i>Wound Rep. Reg.</i> , <u>6</u> :276-290 (1998)
*AB	Takeda <i>et al.</i> , "Construction of a bovine yeast artificial chromosome (YAC) library", <i>Animal Genetics</i> , <u>29</u> :216-219 (1998)
*AC	Tao <i>et al.</i> , "Cloning and stable maintenance of DNA fragments over 300 kb in <i>Escherichia coli</i> with conventional plasmid-based vectors", <i>Nucl. Acids Res.</i> , <u>26</u> (21):4901-4909 (1998)
*AD	Toye <i>et al.</i> , "A yeast artificial chromosome (YAC) library containing 10 haploid chicken genome equivalents", <i>Mammalian Genome</i> , <u>8</u> :274-276 (1997)
*AE	Tsonis <i>et al.</i> , "Regeneration in Vertebrates", <i>Devel. Biol.</i> , <u>221</u> :273-284 (2000)
*AF	Uherek <i>et al.</i> , "DNA-carrier proteins for targeted gene delivery", <i>Adv. Drug Delivery Reviews</i> , <u>44</u> :153-166 (2000)
*AG	Urlaub <i>et al.</i> , "Effect of Gamma Rays at the Dihydrofolate Reductase Locus: Deletions and Inversions", <i>Somatic Cell and Mol. Genetics</i> , <u>12</u> (6):555-566 (1986)
*AH	Wada <i>et al.</i> , "Chimeric YACs were generated at unreduced rates in conditions that suppress coligation", <i>Nucl. Acids Res.</i> , <u>2</u> (9):1651-1654 (1994)
*AI	Zhong <i>et al.</i> , "Zebrafish Genomic Library in Yeast Artificial Chromosomes", <i>Genomics</i> , <u>48</u> :136-138 (1998)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Title: **METHODS FOR DELIVERING NUCLEIC ACID MOLECULES INTO CELLS AND ASSESSMENT THEREOF**